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REMARKS

This is a full and timely response to the outstanding Office action mailed October 6, 2005. Upon entry of the amendments in this response claims 1-13 are pending. More specifically, claim 1 is amended. These amendments are specifically described hereinafter.

I. Present Status of Patent Application

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by *Mena* (U.S. Patent No. 4,762,444). Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by *Longhini et al.* (U.S. Patent No. 6,524,318). Claims 11 and 12 are rejected under 35 U.S.C. 102 (e) as being anticipated by *Longhini et al.* (U.S. Patent No. 6,524,318). Claims 1-4, 6, and 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by *Randall et al.* (U.S. Patent No. 6,635,059). These rejections are respectfully traversed.

II. Rejections Under 35 U.S.C. §102(b)

A. Claims 1-6 and Mena

The Office Action rejects claims 1-6 under 35 U.S.C. §102(b) as allegedly being anticipated by *Mena* (U.S. Patent No. 4,762,444). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

Independent claim 1 as amended recites:

1. A flexible tap apparatus member comprising:
a shaft having a flexible upper shaft portion and a flexible lower shaft portion,
said upper shaft portion comprising ridges and said lower shaft portion
having a substantially smooth surface;
wherein said flexible tap apparatus member is arranged and configured to engage
tissue.

(Emphasis Added).

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For a proper rejection of a claim under 35 U.S.C. §102, the cited reference must disclose, teach, or suggest all elements/features/steps of the claim at issue. *See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988).

Applicant respectfully submits that independent claim 1 as amended is allowable for at least the reason that *Mena* does not disclose, teach, or suggest **a shaft having an flexible upper shaft portion and a flexible lower shaft portion**. The device of *Mena* is not disclosed as flexible. As disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

See Application, page 5, lines 15-18.

The disclosure of *Mena* does not teach any particular composition for the tap, and, specifically, does not disclose a flexible shaft. Therefore, *Mena* does not anticipate independent claim 1, and the rejection should be withdrawn.

Because independent claim 1 is allowable over the cited references of record, dependent claims 2-6 (which depend from independent claim 1) are allowable as a matter of law for at least the reason that dependent claims 2-6 contain all the steps/features of independent claim 1. *See Minnesota Mining and Manufacturing Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002) *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 54 U.S.P.Q.2d 1086 (Fed. Cir. 2000); *Wahpeton Canvas Co. v. Frontier Inc.*, 870 F.2d 1546, 10 U.S.P.Q.2d 1201 (Fed. Cir. 1989). Therefore, since dependent claims 2-6 are patentable over *Mena*, the rejection to claims 2-6 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 1, dependent claims 2-6 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patentably distinct from the cited references of record. Hence there are other reasons why dependent claims 2-6 are allowable.

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B. Claims 1-6 and *Longhini*

The Office Action rejects claims 1-6 under 35 U.S.C. §102(e) as allegedly being anticipated by *Longhini* (U.S. Patent No. 6,524,318). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

Independent claim 1 as amended recites:

1. A flexible tap apparatus member comprising:
a shaft having an flexible upper shaft portion and a flexible lower shaft portion,
said upper shaft portion comprising ridges and said lower shaft portion
having a substantially smooth surface;
wherein said flexible tap apparatus member is arranged and configured to engage
tissue.

(Emphasis Added).

Applicant respectfully submits that independent claim 1 as amended is allowable for at least the reason that *Longhini* does not disclose, teach, or suggest **a shaft having an flexible upper shaft portion and a flexible lower shaft portion**. The device of *Longhini* is not disclosed as flexible. As disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

See *Application*, page 5, lines 15-18.

The disclosure of *Longhini* does not teach any particular composition for the tap, and, specifically, does not disclose that the tap should have a flexible shaft. In fact, *Longhini* teaches away from having a flexible shaft. If the shaft in *Longhini* proves to be flexible, “[s]haft 550 can also include a stabilizer 554 for controlling lateral stability of shaft 550 when within lumen 502

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of tubular sleeve 501." See *Longhini*, col. 12, lines 30-32. As *Longhini* teaches to control the lateral stability of the shaft, it cannot be deemed to teach the use of a flexible shaft. Therefore, *Longhini* does not anticipate independent claim 1, and the rejection should be withdrawn.

Because independent claim 1 is allowable over the cited references of record, dependent claims 2-6 (which depend from independent claim 1) are allowable as a matter of law for at least the reason that dependent claims 2-6 contain all the steps/features of independent claim 1. Therefore, since dependent claims 2-6 are patentable over *Longhini*, the rejection to claims 2-6 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 1, dependent claims 2-6 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Hence there are other reasons why dependent claims 2-6 are allowable.

C. Claims 1-4, and 6 and *Randall*

The Office Action rejects claims 1-4, and 6 under 35 U.S.C. §102(e) as allegedly being anticipated by *Randall* (U.S. Patent No. 6,635,059). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

Independent claim 1 as amended recites:

1. A flexible tap apparatus member comprising:
a shaft having an flexible upper shaft portion and a flexible lower shaft portion,
said upper shaft portion comprising ridges and said lower shaft portion
having a substantially smooth surface;
wherein said flexible tap apparatus member is arranged and configured to engage
tissue.

(Emphasis Added).

Applicant respectfully submits that independent claim 1 as amended is allowable for at least the reason that *Randall* does not disclose, teach, or suggest **a shaft having an flexible**

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upper shaft portion and a flexible lower shaft portion. The device of *Randall* is not disclosed as flexible. As disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

See *Application*, page 5, lines 15-18.

The disclosure of *Randall* does not teach any particular composition for the tap, and, specifically, does not disclose that the tap should have a flexible shaft. In fact, *Randall* teaches away from having a flexible shaft. "For example, the screw 10, nut 40, and washer 50 are the same grade of surgical stainless steel." See *Randall*, col. 4, lines 21-23. One of ordinary skill in the art would not consider surgical stainless steel to be a flexible material as claimed. Therefore, *Randall* does not anticipate independent claim 1, and the rejection should be withdrawn.

Because independent claim 1 is allowable over the cited references of record, dependent claims 2-4 and 6 (which depend from independent claim 1) are allowable as a matter of law for at least the reason that dependent claims 2-4 and 6 contain all the steps/features of independent claim 1. Therefore, since dependent claims 2-4 and 6 are patentable over *Randall*, the rejection to claims 2-4 and 6 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 1, dependent claims 2-4 and 6 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Hence there are other reasons why dependent claims 2-4 and 6 are allowable.

D. Claims 7-8 and 11 and Longhini

The Office Action rejects claims 7-8 and 11 under 35 U.S.C. §102(e) as allegedly being anticipated by *Longhini* (U.S. Patent No. 6,524,318). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

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Independent claim 7 recites:

7. A flexible tap apparatus system comprising:

a first flexible tap apparatus member, comprising:

a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;

wherein said shaft of said first flexible tap apparatus member comprises a first set of dimensions; and

a second flexible tap apparatus member, comprising:

a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;

wherein said shaft of said second flexible tap apparatus member comprises a second set of dimensions;

wherein said first set of dimensions differs from said second set of dimensions.

(Emphasis Added).

Applicant respectfully submits that independent claim 7 is allowable for at least the reason that *Longhini* does not disclose, teach, or suggest **a shaft having a flexible upper shaft portion and a flexible lower shaft portion**. The device of *Longhini* is not disclosed as flexible. As disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

See *Application*, page 5, lines 15-18.

The disclosure of *Longhini* does not teach any particular composition for the tap, and, specifically, does not disclose that the tap should have a flexible shaft. In fact, *Longhini* teaches

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away from having a flexible shaft. If the shaft in *Longhini* proves to be flexible, “[s]haft 550 can also include a stabilizer 554 for controlling lateral stability of shaft 550 when within lumen 502 of tubular sleeve 501.” See *Longhini*, col. 12, lines 30-32. As *Longhini* teaches to control the lateral stability of the shaft, it cannot be deemed to teach the use of a flexible shaft. Therefore, *Longhini* does not anticipate independent claim 7, and the rejection should be withdrawn.

Because independent claim 7 is allowable over the cited references of record, dependent claims 8 and 11 (which depend from independent claim 7) are allowable as a matter of law for at least the reason that dependent claims 8 and 11 contain all the steps/features of independent claim 7. Therefore, since dependent claims 8 and 11 are patentable over *Longhini*, the rejection to claims 8 and 11 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 7, dependent claims 8 and 11 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Hence there are other reasons why dependent claims 8 and 11 are allowable.

E. Claims 7-10 and *Randall*

The Office Action rejects claims 7-10 under 35 U.S.C. §102(e) as allegedly being anticipated by *Randall* (U.S. Patent No. 6,635,059). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

Independent claim 7 recites:

7. A flexible tap apparatus system comprising:
a first flexible tap apparatus member, comprising:
a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;
wherein said shaft of said first flexible tap apparatus member comprises a first set of dimensions; and

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a second flexible tap apparatus member, comprising:
a shaft having a flexible upper shaft portion and a flexible lower shaft
portion, said upper shaft portion comprising ridges and said lower
shaft portion having a substantially smooth surface;
wherein said shaft of said second flexible tap apparatus member comprises
a second set of dimensions;
wherein said first set of dimensions differs from said second set of dimensions.

(Emphasis Added).

Applicant respectfully submits that independent claim 7 is allowable for at least the reason that *Randall* does not disclose, teach, or suggest **a shaft having a flexible upper shaft portion and a flexible lower shaft portion**. The device of *Longhini* is not disclosed as flexible. As disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

See *Application*, page 5, lines 15-18.

The disclosure of *Longhini* does not teach any particular composition for the tap, and, specifically, does not disclose that the tap should have a flexible shaft. In fact, *Longhini* teaches away from having a flexible shaft. If the shaft in *Longhini* proves to be flexible, “[s]haft 550 can also include a stabilizer 554 for controlling lateral stability of shaft 550 when within lumen 502 of tubular sleeve 501.” See *Longhini*, col. 12, lines 30-32. As *Longhini* teaches to control the lateral stability of the shaft, it cannot be deemed to teach the use of a flexible shaft. Therefore, *Randall* does not anticipate independent claim 7, and the rejection should be withdrawn.

Because independent claim 7 is allowable over the cited references of record, dependent claims 8-10 (which depend from independent claim 7) are allowable as a matter of law for at

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least the reason that dependent claims 8-10 contain all the steps/features of independent claim 7. Therefore, since dependent claims 8-10 are patentable over *Randall*, the rejection to claims 8-10 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 7, dependent claims 8-10 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Hence there are other reasons why dependent claims 8-10 are allowable.

F. Claim 12

The Office Action rejects claim 12 under 35 U.S.C. §102(e) as allegedly being anticipated by *Longhini* (U.S. Patent No. 6,524,318). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

Independent claim 12 recites:

12. A method of creating a passage in tissue comprising:
providing a flexible tap apparatus system comprising:
a first flexible tap apparatus member, comprising:
a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;
wherein said shaft of said first flexible tap apparatus member comprises a first set of dimensions; and
a second flexible tap apparatus member, comprising:
a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;
wherein said shaft of said second flexible tap apparatus member comprises a second set of dimensions;
wherein said first set of dimensions differs from said second set of dimensions;

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engaging said first flexible tap apparatus member into the tissue;
disengaging said first flexible tap apparatus member from the tissue; and
engaging said second flexible tap apparatus member into the tissue.

(Emphasis added).

Applicant respectfully submits that independent claim 12 is allowable for at least the reason that *Longhini* does not disclose, teach, or suggest at least **providing ... a shaft having a flexible upper shaft portion and a flexible lower shaft portion**. The device provided in *Longhini* is not disclosed as flexible. As disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

See *Application*, page 5, lines 15-18.

The disclosure of *Longhini* does not teach any particular composition for the tap, and, specifically, does not disclose that the tap should have a flexible shaft. In fact, *Longhini* teaches away from having a flexible shaft. If the shaft in *Longhini* proves to be flexible, “[s]haft 550 can also include a stabilizer 554 for controlling lateral stability of shaft 550 when within lumen 502 of tubular sleeve 501.” See *Longhini*, col. 12, lines 30-32. As *Longhini* teaches to control the lateral stability of the shaft, it cannot be deemed to teach the use of a flexible shaft. Therefore, *Longhini* does not anticipate independent claim 12, and the rejection should be withdrawn.

III. Miscellaneous Issues

Claim 13 was not addressed in the Office Action. Therefore, Applicant respectfully asserts that claim 13 is allowable over the cited references. Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted.

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CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1-13 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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